



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 7, 2017

Georgia Anastasiou
Agent for Abbott Laboratories
Abbott Laboratories
c/o Lewis and Harrison
122 C St. NW, Suite 505
Washington, DC 20001

Subject: Label Amendment – Changes to precautionary statement and directions for use
Product Name: ICQ c-series Water Bath Additive
EPA Registration Number: 275-3
Application Date: July 6, 2017
Decision Number: 531925

Dear Ms. Anastasiou:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

Sincerely,



Zeno Bain, Acting Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

ICQ c-series Water Bath Additive

FOR U.S. CUSTOMERS ONLY

EPA Reg. No. 275-3

EPA Est. No. 75612-CAN-002

For use with the Alinity c-series analyzers

This product is used to prevent and control microbial contamination in the water bath

Active Ingredients:

5-Chloro-2-methyl-4-isothiazolin-3-one	0.2184%
2-Methyl-4-isothiazolin-3-one	0.0777%
Inert Ingredients:	99.7039%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. (Remove contact lenses, if present, after the first 5 minutes then continue rinsing the eye.) Call a poison control center or doctor for treatment advice.

If on skin and/or on clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Important: Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

PREPARATION FOR USE

1. ICQ c-series Water Bath Additive is ready-to-use.
2. Verify that the bottle has not leaked.
3. Remove the black cap by turning the cap counterclockwise until the cap stops.
4. Align the tabs on the cap with the grooves in the cartridge and pull the cap to remove it.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

The Alinity c-series Maintenance Solutions cartridge, containing the c-series Water Bath Additive, is placed in the analyzer loading area, then loaded into the analyzer. The ICQ c-series Water Bath Additive is automatically dispensed into the water bath during specific operations which control microbial contamination in the water bath. Do not use this product as a disinfectant.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Causes moderate eye and skin irritation. Harmful if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Wear protective eyewear and chemically resistant gloves when handling this product. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

USER SAFETY RECOMMENDATIONS

User should: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove clothing immediately if product gets inside, then wash thoroughly and put on clean clothing. Remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly.

ENVIRONMENTAL HAZARDS

This chemical is toxic to terrestrial and aquatic plants, fish and aquatic invertebrates.

(Note to Reviewer: This product is only packaged in containers that are one gallon or less in size. As a result, the following storage and disposal statements are used.)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store at 15-30°C in original packaging.

Product Disposal: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Handling: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or discard in trash.

Net Contents:

Bottle:

Carton:

(Note to Reviewer: Batch code information will appear either on the container or on the label.)

Batch Code: _____

Distributed by:
ABBOTT Laboratories
100 Abbott Park Road
Abbott Park, IL 60064

Cartridge Label

Note to reviewer – the product is sold in small cartridges that only allow approximately 2.3 fl oz. of product.

ICQ c-series Water Bath Additive

EPA REG. NO. 275-3 EPA EST. NO. 075612-CAN-002

Active Ingredients: 5-Chloro-2-methyl-4-isothiazolin-3-one
0.2184%, 2-Methyl-4-isothiazolin-3-one 0.0777%, Inert
Ingredients: 99.7039%

Keep Out of Reach of Children
CAUTION

Refer to accompanying label on outer box for complete information.

2.3 fl oz (68.4 mL)

Kit Label

Note to reviewer – the product will be sold in a kit with a cleaning solution that is regulated by FDA. The following language will appear as part of the of the kit label. The language/graphics are FDA requirements. The full EPA label will be visible on the outer package as well.

Alinity c-series Maintenance Solutions
ICQ c-series Water Bath Additive 10 x 68.4 mL
Alinity c-series Lyophilized Cleaning Solution 10 x 12 mL
Alinity c-series Cleaning Solution 1 x 150mL
Contains: Azide

INTENDED USE

The Alinity c-series Maintenance Solutions are used to perform the automated daily maintenance procedure and selected diagnostic procedures on the Alinity c analyzer. ICQ c-series Water Bath Additive is an antimicrobial solution used to prevent and control microbial contamination in the water bath. Cleaning Solution is a cleaning solution used to remove protein from sample and reagent probes, mixers, the ICT probe and the ICT module.

